UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR PROTECTIVE ORDER CONCERNING PLAINTIFFS' SUBPOENAS TO THIRD-PARTY MANUFACTURERS OF PATIENT WARMING DEVICES**

Plaintiffs respectfully request the Court deny Defendants' attempt to deny Plaintiffs' discovery of relevant evidence by moving this Court for a Protective Order.

The dispute facing the Court is quite different than non-party VitaHEAT's challenge Plaintiffs' subpoena. Because Defendants are not the subject of the subpoenas, Defendants are limited in the objections they can assert. Unlike the subpoenaed entities, which have standing to challenge the discovery on any grounds, Defendants' only stake in the matter is its "right to reasonable discovery and efficient disposition of the case." *Shukh v. Seagate Technology, LLC*, 295 F.R.D. 228, 236 (D.Minn.2013). Thus, the only issue "is one of case management under Rules 16 and 26." *Id.* To be entitled to protection, Defendants must be able to show the document requests are so harmful to 3M as to threaten its right to reasonable discovery. In truth, 3M would suffer no real harm from these limited document requests to third parties, which are miniscule in nature compared to the overall scope of discovery. Rather, Defendants' motive is to prevent Plaintiffs from acquiring potentially damaging admissible evidence about safer patient warming products. Plaintiffs respectfully request the Court deny Defendants' attempt to obstruct this discovery.

BACKGROUND

Plaintiffs served subpoenas regarding six alternatively designed patient warming systems. Two of these patient-warming systems (Mistral-Air and WarmAir) utilize a blower design to transfer heat to the blanket, providing conductive, radiant, and convective heat to the patient. Four of these patient-warming systems (Blanketrol II, PerfecTemp, Medi-Therm, and Allon) utilize an electrical design to transfer heat to the blanket, providing conductive and radiant heat to the patient.

With respect to the patient warming devices which principally emphasize conductive heat transfer to the patient, none of the manufacturers have objected to the subpoenas. Nonetheless, even in the absence of an objection or any burden, Plaintiffs recognize that the Court may be inclined to apply the same standard applied by Judge Noel in his March 6, 2017 order sustaining non-party VitaHEAT's objection.[1] However, Plaintiffs believe what constitutes a "patient warming device" has not been properly defined, particularly in light of recent testimony from 3M's corporate representative relating to heat transfer mechanics and the Bair Hugger's use of conductive warming. Moreover, Plaintiffs believe that the issue of fundamental similarity between products and feasibility of product re-design are questions of fact which are not ripe in the discovery context. Plaintiffs hope to present additional briefing and argument on these issues to the Court, but for purposes of this response will confine argument to the two patient warming products that share a blower design concept with the Bair Hugger: the Mistral-Air system and the WarmAir system.

In seeking to block these two subpoenas, 3M invoked Plaintiffs' "threshold burden" of relevance, but the burden is not high in this context: "[I]f Plaintiffs' requests are reasonably calculated to lead to the discovery of evidence regarding a feasible design that is safer than the

[1] Plaintiffs have filed a letter requesting leave to seek reconsideration of the March 6, 2017 order.

[defendant's] design, then those requests satisfy Plaintiffs' threshold burden of establishing relevance." *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 2010 WL 234797, at *2 (M.D.Ga. 2010). In this case, discovery regarding the Mistral-Air device and the WarmAir device are reasonably calculated to produce evidence regarding devices which are safer than the Bair Hugger. Both devices are patient warming products used to accomplish similar patient outcomes. Moreover, like both Augustine Medical's "HotDog" and VitaHeat's "UB3" warming systems, the Mistral and WarmAir have been found by the FDA to be among a group of "substantially equivalent" patient warming products.

ARGUMENT

I. Plaintiffs' Subpoenas Regarding Mistral-Air and WarmAir are Relevant and Reasonable.

With respect to patient warming devices which share the Bair Hugger's blower design component, the Mistral-Air system and the WarmAir system, it is facially clear that these products are potentially safer alternative designs to the Bair Hugger. "[Q]uestions concerning alternative designs for the product are clearly relevant and discoverable." *Haensel v. Chrysler Corp.*, 1997 WL 537687, at *4 (E.D. La. Aug. 22, 1997). Both of these devices are marketed as safer alternatives with numerous design and performance claims. Discovery relating to these two products is likely to produce evidence relevant to Plaintiffs' defect allegations.[2]

A. Mistral-Air Patient Warming System

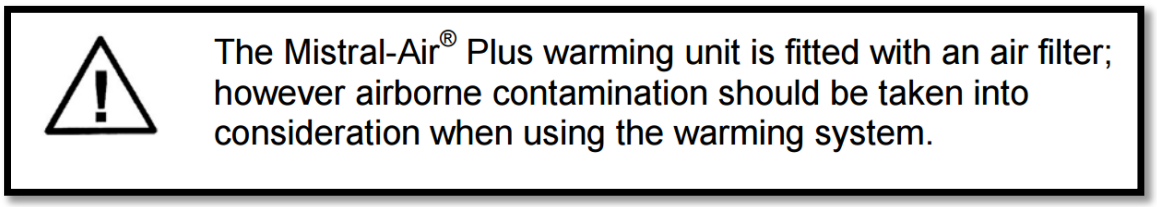
Mistral-Air, manufactured by Stryker, is explicitly marketed as a safer alternative to the Bair Hugger. Stryker promotes the Mistral-Air by featuring its HEPA filter.[3] As this Court recently held, "a conductive patient warming device with the addition of a HEPA filter, for example, could be relevant if so contended by Plaintiffs." *See* Doc. 249, n. 2. Not only does

[2] *See* Plaintiff's Master Long Form Complaint, at p. 4, 11, 14, 22-23, 26, 31.
[3] *See* Mistral-Air marketing materials, attached as Exhibit 1 to Declaration of Genevieve Zimmerman.

Stryker advertise the use of HEPA filtration, but it also makes several other claims about the advanced design of the device. For example, Mistral-Air marketing materials state that:

> The Mistral-Air warming blankets and suits and Mistral-Air Plus Warming Unit are attuned to each other. This ensures smart warming, optimum performance, and equal distribution of warm air throughout the entire blanket.[4]

Marketing materials also state that Mistral-Air blankets "use controlled diffusion" and are capable of "preventing airflow obstruction."[5] Discovery of the design details and testing underlying these descriptions is relevant to the defects alleged by Plaintiffs, which includes the distribution of air and heat. Moreover, discovery served on Stryker regarding the Mistral are relevant to Plaintiffs' allegations regarding Defendants' failure to warn; the Mistral-Air service manual[6] contains the following warning:



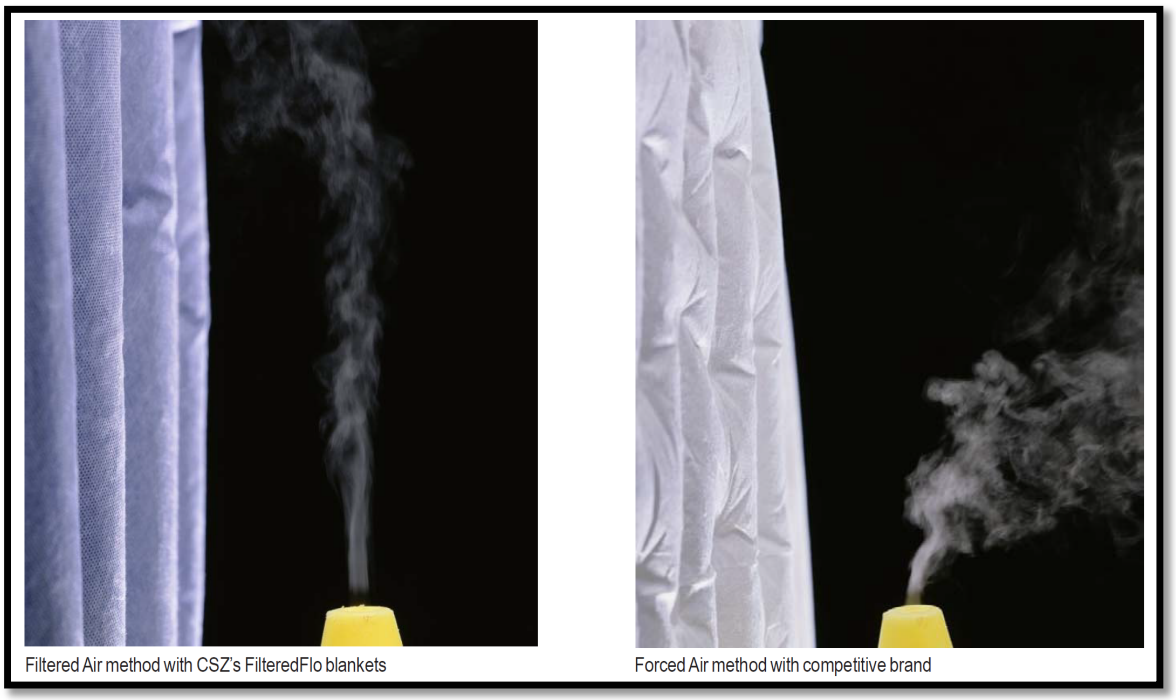
Given the presence of this warning and the numerous design claims made by the manufacturer, the Mistral-Air patient warming system as a whole is relevant to defect allegations made in Plaintiffs' complaint.

B. WarmAir Patient Warming System

The second device at issue is the WarmAir patient warming system, manufactured by Cincinnati Sub Zero. This device is also marketed as a safer alternative to the Bair Hugger. Marketing materials not only tout the presence of a HEPA filter, but also discuss a "FilteredFlo

[4] *Id.*
[5] *Id.*
[6] *See* Exhibit 2, Mistral MA-1110 service manual.

blanket" which features a "non-woven delivery surface."[7] These blankets have "no perforation," are designed to avoid "unwanted and potentially dangerous particles in your operating room."[8] The manufacturer states that the blanket design also "permits use of a lower velocity blower to supply gently moving, clean air" which "minimizes air currents that may spread contaminants to your patient."[9] [redacted] WarmAir advertising also features photographs of air current demonstrations:



There are many other potential ways in which the Mistral-Air system or the WarmAir system may be safer than the Bair Hugger beyond those which are explicitly described to the public. Because Plaintiffs have not yet conducted discovery on these devices, Plaintiff is not yet

[7] *See* Exhibit 3, WarmAir marketing brochure.
[8] *Id.*
[9] *Id.*
[10] *See* Exhibit 4, 3M internal email, 3MBH00844487.

in a position to determine with specificity how these devices operate as a system, nor provide the Court with precise details about the performance of these alternative designs. For these reasons, 3M's attempts to limit discovery to specific components is overly narrow. [redacted]

Accordingly, Plaintiffs' subpoenas seeking information about the Mistral-Air and WarmAir devices as complete patient warming systems are appropriate and permissible attempts to obtain discovery of evidence regarding the safety of these alternatively designed patient warming devices.

CONCLUSION

"A competitor's contemporaneous use of the proposed design alternative for the same purpose in the same consumer market is sufficient evidence to establish a genuine issue of fact as to the existence of a feasible design alternative." *Standard Fire Ins. Co. v. Broan Nutone, LLC,* No. 2:07CV44–KS–MTP, 2008 WL 5560882, at *6 (S.D.Miss. July 1, 2008). Because the Mistral and WarmAir patient warming systems are both potential alternative designs with broad advertising claims about their safer features vis-a-vis the Bair Hugger patient warming system, Plaintiffs' discovery requests are proper. Plaintiffs' subpoenas are tailored to lead to admissible evidence on the design, testing, and even warnings of these two devices. Moreover, Plaintiffs

[11] *See* Exhibit 5, MDL Deposition of Teri Woodwick-Sides 104:4.
[12] *Id.* at 123:24.

hope for the opportunity to show the Court that there is sufficient evidence that patient warming systems which utilize a resistive blanket design element are also fundamentally similar patient warming products, used for the same purpose in the same consumer market, and should be likewise discoverable. Accordingly, Plaintiffs respectfully request the Court deny Defendants' motion for a protective order.

Respectfully submitted,

Dated: March 17, 2017

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